

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Introduction

Claims 19, 21, 32, 34, 35, 45, 51, 63, 65, 79, 84, 86 and 88 have been amended to delete the term “about.” Claims 45 and 63 have been amended to recite that the surface stabilizer is adsorbed on the surface of the particles. Exemplary support for this amendment can be found in the specification, e.g., at page 6, lines 15-16. Claims 50 and 64 have been amended to delete the recitation of “a semi-amorphous phase, and mixtures thereof.” Claims 60 and 75 have been amended to replace the trademarks with their corresponding generic chemical names. Claims 1 and 78 have been amended for greater clarity.

Applicants acknowledge the finality of this Office Action. Nevertheless, because the amendments to the claims do not introduce any new matter or require any additional search, and because they either place the application in condition for allowance or in better condition for appeal, Applicants respectfully request entry of this amendment. Upon entry, claims 1-31, 36-38, 40 and 44 are under examination, with claims 32-35, 39, 41-43, and 45-95 withdrawn.

According to the Office Action issued on September 5, 2007, claims 32-35, 39, and 41-43 are withdrawn as they are directed to non-elected species. Upon allowance of a generic claim, Applicants respectfully request that the claims directed to non-elected species be rejoined for examination in the present application.

Moreover, claims 45-62 (drawn to a method of making the nimesulide composition) and claims 63-95 (drawn to a method of treating a subject using the nimesulide composition) are related to claims 1-44 as product and process claims (Office Action dated January 9, 2007).

Applicants respectfully request rejoinder of the process claims upon allowance of the product claims for examination in the present application.

II. Rejection of Claims under 35 U.S.C. § 112, second paragraph

Claims 19 and 21 remain rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Applicants respectfully traverse the rejection.

Specifically, the Examiner asserts that the combined use of the terms “at least” and “about” to describe the C_{\max} and AUC renders the claims indefinite. Without acquiescing to the stated rationale of the rejection, Applicants choose to advance the prosecution by deleting the term “about” in the claims at issue. Accordingly, withdrawal of the rejection is respectfully requested.

III. Rejection of Claims under 35 U.S.C. § 102(e)

Claims 1-14 and 27-31 remain rejected under 35 U.S.C. § 102(e) for alleged anticipation by PCT Publication No. WO 2005/000273 by Olivieri et al. (“Olivieri”). Applicants respectfully traverse the rejection.

Olivieri is not citable art against the claimed invention. Olivieri was filed on June 27, 2003 and did not claim priority to any other applications. On the strength of the accompanying declaration executed by the co-inventor Dr. William Bosch, Applicants have demonstrated that the claimed invention was reduced to practice prior to June 27, 2003, which is the filing date of the cited art.

Swearing behind a reference only requires prior reduction to practice of a single embodiment within the scope of the claimed invention. *See* MPEP 715.02, which states that “[t]he 37 C.F.R. §1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus), in

the sense that the claim as a whole reads on it.” Therefore, the contents of the Bosch Declaration meet the requirements for a 37 C.F.R. §1.131 affidavit or declaration.

Furthermore, a declaration under 37 C.F.R. §1.131 only needs to be signed by the person corroborating that a prior reduction to practice has occurred. See MPEP 715.07(a), which states that in a 37 C.F.R. §1.131 affidavit or declaration, corroboration is not required and an applicant may stand on his or her own affidavit or declaration if he or she so elects. Therefore, it is not necessary for the declaration to be signed by all the inventors.

Accordingly, Olivieri has been disqualified as citable art against the present application. For this reason alone, the rejection under 35 U.S.C. § 102(e) should be withdrawn.

IV. Rejection of Claims under 35 U.S.C. § 103(a)

A. Olivieri and Liversidge

Claims 1, 10-13 and 15-26 are rejected under 35 U.S.C. § 103(a) for alleged obviousness over Olivieri in view of U.S. Patent No. 5,552,160 to Liversidge et al. (“Liversidge”). Applicants respectfully traverse the rejection.

B. Olivieri, Singh and MERCK

Claims 1, 36-38 and 40 are rejected under 35 U.S.C. § 103(a) for alleged obviousness over Olivieri in view of Singh et al., *Analytical Profiles of Drug Substances and Excipients* 28: 197-249, 2001 (“Singh”), and in view of the Merck Index, 12th ed., Merck & Co. codeine, pp. 416-417, 1996 (“MERCK”). Applicants respectfully traverse the rejection.

C. Olivieri and Buhl

Claims 1 and 44 are rejected under 35 U.S.C. § 103(a) for alleged obviousness over Olivieri in view of U.S. Patent No. 5,776,563 to Buhl et al. ("Buhl"). Applicants respectfully traverse the rejection.

All obviousness rejections raised in the Final Office Action are based on the common primary reference, Olivieri. Pursuant to MPEP 715.02, "[a]pplicant may overcome a 35 U.S.C. 103 rejection based on a combination of references by showing completion of the invention by applicant prior to the effective date of any of the references." As discussed *supra*, Olivieri is not citable art against the claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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